AusBiotech
AUSTRALIA'S BIOTECHNOLOGY ORGANISATION

21 November, 2008

The Regulator
Office of the Gene Technology Regulator
MDP 54
GPO Box 9848
CANBERRA, ACT, AUSTRALIA,
2601

RE: Review of the Gene Technology Regulations 2001

Dear Regulator,

AusBiotech, Australia's Biotechnology Industry Organisation, represents over 3,000 members covering the human health, agricultural, medical device, bioinformatics, environmental and industrial sectors in biotechnology. As such, we are providing some comments regarding the current review of the Gene Technology Regulations 2001.

Categorisation of dealings

1. Definition of a pathogen

Agents that are considered to have caused disease may not be included in a Notifiable Low Risk Dealing. The current wording used to describe a pathogen is an agent that "has been implicated in, or has a history of causing, disease in human beings, animals, plants or fungi" (NLRDs; Schedule 3). This definition is problematic as the ability of an organism to cause disease is a function of the health of the hosts immune system and the environment.

It could be interpreted that the definition that most of the agents that are currently listed in Schedule 2 Part 2 of the Regulations as host/vector systems for exempt dealings are pathogenic, especially in immune compromised individuals, irrespective of the long history of safe use. Therefore, AusBiotech considers that the current definition is not appropriate and requires amendment to reflect that that majority of researchers handling these vectors have a normal and healthy immune system.

Recommendation 1
The wording that defines pathogenic agents in the Regulations ("the host or vector has been implicated in, or has a history of causing, disease in human beings, animals, plants or fungi") be replaced throughout with "the host or vector is able to cause disease in an otherwise healthy human, animal, plant or fungal host".

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Recommendation 2
The definition of pathogenic that appears, in Regulation 3, as "in relation to an organism, means having the capacity to cause disease or abnormality" be replaced with "in relation to an organism, means having the capacity to cause disease or abnormality in an otherwise healthy human, animal, plant or fungal host".

2. Definition of pathogenic determinants.
Almost any characteristic of an infectious agent can be said to affect the ability of that agent to cause disease or abnormality. Modification of the cell walls, the ability to use alternate carbon source may increase an infectious agent's chance of survival in a host and so influence its ability to cause disease however these traits may also come with a metabolic penalty. In general, the risks associated with modifications of this sort not significant when compared to modifications that introduce a new adhesion molecule, toxin or protein that are well known factors leading to damage in its host. As such, the wording in the Regulations should reflect this understanding.

Recommendation 3
That the definition of pathogenic determinant be amended to read "means a characteristic that is known to increase the capacity of a host or vector to cause disease or abnormality" to improve the scientific correctness of the Regulations.

3. Simplification of wording surrounding PC2 plant containment facilities.
There is an element of confusion surrounding wording of the section that defines PC2 NLRD type (b) (Schedule 3, Part 2, 2.1 (b)) as amended in the last review of the Regulations that deals with GM plants activities conducted in PC2 certified plant houses.

The OGTR guidelines for the certification of PC2 plant containment facilities are based on requirements in AS/NZS 2243.3 (Safety in laboratories Part 3; microbiological aspects and containment facilities). The current wording surrounding NLRD type (b) states that a "facility designed to prevent the escape of GM material" is required. It would be clearer if the wording simply stated that "dealings must be conducted in a PC2 certified plant house".

Recommendation 3
The wording of Schedule 3, Part 2, 2.1 (b) be replaced with "…in a certified PC2 facility that prevents the escape from the facility of…"

3. Modifications to Schedule 3 to clarify the classification of complementation experiments.
The current description surrounding the modification to the virulence of organisms by down regulating genes then re-activating them (complementation experiments) is complex and can be simplified.

By modifying 2.1(d) to make a reference to the virulence of parent strains; removing 2.1(g) – which is in part conflict with 2.1(d); altering Schedule 3 Part 3, 3.1 (e)(ii); deleting 3.1 (e)(iii) and changing 3.1(f)(i)) would make this part of the Regulations much clearer.

Recommendation 3
- Schedule 3, Part 2, (d)(ii) be modified to read "…or increase the virulence, pathogenicity or transmissibility of the host or vector above that of the parent organism";

- Schedule 3, Part 2, 2.1(g) be deleted;
- Schedule 3, Part 3, 3.1(e)(ii) be modified to read "…or increase the virulence, pathogenicity or transmissibility of the host or vector above that of the parent organism";
- Schedule 3, Part 3, 3.1(e)(iii) be deleted;
- Schedule 3, Part3, 3.1(f)(i) be modified to read "the donor nucleic acid is characterised and is not known to increase the host range or add a mode of transmission, or increase the virulence, pathogenicity or transmissibility of the host above that of the parent organism"

By using these modifications to the Regulations, researchers can be confident that their dealing is classified as PC2 NLRD type (d), without needing to refer to Schedule 3 Part 3. By comparing the increase in virulence, pathogenicity or transmissibility relative to that seen in the parent strain, AusBiotech is of the opinion that these changes will not increase risk, while improving the ability of researchers to understand the Regulations.

4. The role of the IBC in reporting and the type of information required for forms.

The wording used in the current regulation makes the recording, reporting and communication of decisions about NLRDs the responsibility of an Institutional Biosafety Committee (IBC). As organisations are identified and accredited it would be more sensible that this responsibility is transferred to the accredited organisation from the IBC. This means that the maintenance of records, IBC's decisions and providing these records to the OGTR as required, communicating results of IBC decisions to project supervisors or other accredited organisations are to domain of the Accredited Organisation. This change also reduces the liability that IBC's have to accept.

Other matters

Licence variation

The OGTR has made some suggestion regarding the timeframe for the Regulator to decide on an application to vary a licence (Regulation 11A). It is appropriate to apply similar provisions to that relating to licence applications at regulation 8 to this particular regulation in terms of "stoping the clock" when information has been requested from an applicant.

AusBiotech, however, does not support a "stop clock" while local councils are developing a response to the regulator. There are several reasons for this, firstly councils may use this mechanism to delay variations irrespective of risk, second the applicant has no ability to influence the timeliness of a response; and thirdly the council has no legal obligations to assess the health and safety of an activity, rather it is there to provide timely advice to the regulator. The ability for any agency to provide advice regarding an application should be factored in based on the complexity of the variation and any additional risk that the variation brings into the licence.

CCI application assessment timeframe

Under Part 3, Division 1, clause 8 (2) (d), a "stop clock" will be imposed when the Regulator has to consider issues related to applications to protect some information as Confidential Commercial Information (CCI). What is not clearly defined is when the "stop clock" may be lifted, allowing the Regulator an undefined period of time to consider the application. To ensure transparency in process, AusBiotech suggests

that a specified period be included (eg 30 days) in which CCI applications must be assessed.

Timeframe for the GT Ethics committee to considering a request from the Regulator

Under Part 3, Division 1, clause 2 (e) and 3, a "stop clock" may be imposed when the Regulator requests the Ethics Committee to provide advice. At present, the period of time considered "reasonable" by the Regulator for the Committee to consider the request is not specified. It would be preferable that a "reasonable period" should be specified in the Regulations (for example, 30 days would be considered reasonable as a maximum time frame) providing clarity for the Regulator, the GT Ethics committee and any application affected by such considerations.

AusBiotech supports the current regulatory process and congratulates the OGTR on maintaining a detailed and scientifically based Risk Assessment of applications made to the Regulator.

Yours sincerely,

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